

K073142

1.4 510(k) Summary of Safety and Effectiveness

Submitted by: Kam Leung, Ph.D., RAC
Senior Regulatory Affairs Specialist

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JAN 11 2008

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Date of Submission: November 6, 2007

Classification Name: Endosseous dental implant (21CFR872.3640)

Trade or Proprietary
or Model Name: NobelReplace Hexagonal Implant

Legally Marketed Device(s): NobelReplace Tapered Conical Connection (K062566)

Device Description:

NobelReplace Hexagonal Implants are threaded, root-form dental implants intended for use in the upper and lower jaw arches to support prosthetic devices, such as an artificial tooth, in order to restore esthetics and chewing function to partially or fully edentulous patients.

The NobelReplace Hexagonal Implants are similar in design to the implants cleared under NobelReplace Tapered Conical Connection, K062566. The predicate internal square was changed to internal hexagonal connection.

Indications for Use:

Nobel Biocare's NobelReplace Hexagonal Implants are endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. The NobelReplace Hexagonal Implants are indicated for single or multiple unit restorations. The NobelReplace Hexagonal Implants can be used in splinted or non-splinted applications. The NobelReplace Hexagonal Implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.



JAN 11 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nobel Biocare AB
C/O Kam Leung, Ph.D., RAC
Senior Regulatory Affairs Specialist
Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K073142
Trade/Device Name: NobelReplace Hexagonal Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: DZE
Product Code: II
Dated: January 7, 2008
Received: January 8, 2008

Dear Dr. Leung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", with a stylized, cursive script.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure


1.3 Indication for Use

510(k) Number (if known):

Device Name: NobelReplace Hexagonal Implants

Indication For Use:

Nobel Biocare's NobelReplace Hexagonal Implants are endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. The NobelReplace Hexagonal Implants are indicated for single or multiple unit restorations. The NobelReplace Hexagonal Implants can be used in splinted or non-splinted applications. The NobelReplace Hexagonal Implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.


(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073142

Prescription Use ☒
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ☐
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)